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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,611	03/29/2004	Atsushi Suzuki	251067US0CONT	9751

22850 7590 09/12/2007

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EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	**PAPER NUMBER**
1614	

NOTIFICATION DATE	DELIVERY MODE
09/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/810,611	SUZUKI ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/22/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,7,8, 11 and 13-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,7,8,11 and 13-31* is/are rejected.

7)☐ Claim(s) _ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/161739.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114.

2. Acknowledgement is made of applicant's filing of amendment filed on 05/22/07. By the amendment, claims 4 and 11 have been amended; claim 12 has been cancelled; and claims 20-31 have been newly added. Accordingly, claims 4, 7-8, 11 and 13-31 are currently pending for prosecution on the merits.

3. Upon further consideration of the claiming subject matter, the examiner's previous indication of allowable subject matter (claims 7-8) in O.A mailed 08/18/06 has been withdrawn.

4. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Rejections - 35 USC § 102

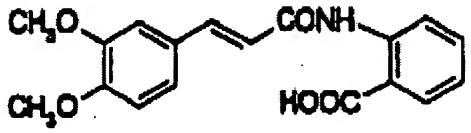
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 4, 7-8, 13-14, 17, 19, 20-23, 26, 29 and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Cheng et al. (The Chinese Pharmaceutical Journal, 1994, 46, pp. 575-582).

Cheng teaches a use of a composition or extract comprising caffeoylquinic acid such as 3,4-dicaffeoylquinic acid, 3,5-dicaffeoylquinic acid, 3,4-dicaffeoylquinate and 4,5-dicaffeoylquinate, chlorogenic acid, methylchlorogenate, methyl caffeate and protocatechuic acid isolated from L. Japonica plant for the treatment of hypertension, wherein said compound is administered intravenously (i.v.) in dosage of 0.1 to 60mg/kg (abstract and pages 577-581).

6. Claims 4, 7, 11-17 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Iwaki et al. (WO 200113911 A1).



(I)

Iwaki teaches a use of or its salt or solvate (commonly known as N-(3,4-dimethoxycinnamoyl)anthranilic acid or tranilast) for the treatment of hypertensive arteriolar disorders including ocular hypertension and hypertensive retinopathy, wherein said composition is administered in various dosage forms including oral, parenteral or eye drop (ophthalmic solution) in dosage range of from 100 to 1000mg per day (oral) or from 20 μg to 300mg per day (parenteral). See abstract and page 3, line 19 through page 4, line 14.

Since tranilast (which is a synthetic derivative of tryptophan) still "metes and bounds" of the applicant's term "an amide bond residue derived from a water soluble amino acid", the examiner maintains the rejection of the record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 18, 20-21 and 23-31 rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaki et al. (WO 200113911 A1) in view of Lennox et al. (US 6046239), and further in view of Iwaki et al. (US 6180673) and Isaji et al. (US 6407139 B1).

The teaching of Iwaki has been discussed in above 35 USC 102(a) rejection. However, Iwaki (WO 200113911 A1) is silent about the substitution of "a hydrogen atom, an alkenyl group, cycloalkyl group, a cyclakenyl group..." at one of R1 or R2 position and the specific dosage amount of 0.001 to 50 wt%.

Lennox is being supplied as reference to demonstrate the routine knowledge in modification of R2 and R1 with hydrogen, alkyl, alkenyl, cycloalkyl, cycloalkenyl, alkoxyalkyl, aryl, alkylaryl or aralkyl group is within the skill of artisan (USP'239 discloses anthranilic acid analogs having "hydrogen, alkyl, alkenyl, cycloalkyl, cycloalkenyl, alkoxyalkyl, aryl, alkylaryl or aralkyl group" at R1, R2 or R3 position). See abstract; column 1, lines 45-48; column 2, line 15 through column 3, line 66; column 31, line 64).

Iwaki (US'673) and Isaji (US'139) are being supplied as references to demonstrate the routine knowledge in preparing tranilast in the amount of "0.001 top 50 wt%" is within the skill of artisan (USP'673 discloses "0.001-2 weight %" of tranilast (see column 4, lines 29-33 and 51-54); and USP'139 discloses "the range of from 100 to 1000 mg per day" in case of oral administration, "the range of from 20 μg to 300mg per day" in case of parenteral administration and about 0.5% of tranilast solution (see column 4, line 27 through column 5, line 17 and Examples)).

One having ordinary skill in the art would have been motivated to combine the references and make such modification with reasonable expectation as taught by Lennox that substitution of methyl with "a hydrogen atom, an alkenyl group, cycloalkyl group, a cyclakenyl group..." would not significantly alter the analogous properties of the referenced anthranilic acid derivative such as tranilast due to close structural similarity of the compounds.

With respect to the determination of the specific amounts, such optimization of known active ingredient in said composition is well within the skill of the artisan, and the skilled artisan would have been motivated to determine optimum dosage amounts to maximize the efficacy of the drug.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

8. No Claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614